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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/989,995	11/21/2001	Ben A. Arnold	IMAGE.011A	1739
20995	7590	11/02/2004	EXAMINER	
KNOBBE MARTENS OLSON & BEAR LLP			TABATABAI, ABOLFAZL	
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IRVINE, CA 92614			2625	

DATE MAILED: 11/02/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/989,995

Applicant(s)

ARNOLD, BEN A.

Examiner

Abolfazl Tabatabai

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on application filed November 21, 2001.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-29 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) _____ is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 21 November 2001 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- ☒ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date 10/31/04.
- ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- ☐ Notice of Informal Patent Application (PTO-152)
- ☐ Other: _____.

DETAILED ACTION

Claim Rejections - 35 USC § 103

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

2. Claims 1, 2 and 3 are rejected under 35 U.S.C. 103(a) as being unpatentable over Erbel (U S 6,792,074 B2) in view of Leigh et al (U S 5,402,785).

Regarding claim 1, Erbel discloses a method of determining tissue densities from computed tomography images, the images containing voxel representations of x-ray attenuation of a subject's body, the method comprising:

acquiring at least one CT image of the subject's body and a calibration phantom simultaneously (column 5, lines 14-23);

determining a CT measure of at least one region of the phantom (column 5, lines 14-23);

applying the calibration relationship to the image (column 4, lines 39-49); and,
recording a calibrated image (column 5, lines 14-23).

However, Erbel is silent about the specific details regarding the steps of:

locating a region of the image containing blood or heart tissue;

determining a CT measure of at least one region located within blood or heart tissue;

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combining the CT measures of the phantom and the CT measure of the blood to develop a calibration relationship;

In the same field (medical image) of endeavor, however, Leigh discloses a method for measuring perfusion using MRI comprising the steps of:

locating a region of the image containing blood or heart tissue (column 4, lines 56-63);

determining a CT measure of at least one region located within blood or heart tissue (column 3, lines 19-21 and column 4, lines 53-55); and,

combining the CT measures of the phantom and the CT measure of the blood to develop a calibration relationship (column 12, lines 23-26 and 34-40).

It would have been obvious to a person of ordinary skill in the art at the time the invention was made to use locating a region of the image containing blood, measures of at least one region located within blood and combining the measurement as taught by the Leigh in the system of Erbel because Leigh provides Erbel an improve system with advantageous of the measuring perfusion of a fluid such blood into a substance such a tissue, and subjecting the fluid to electromagnetic energy so as to cause a response related to the magnetization of the fluid before it enters the substance, performing magnetic resonance measurements on the substance to generate intensity information and processing the intensity information to determine perfusion.

Regarding claim 2, Erbel discloses the method of claim 1 wherein the CT measure is the mode of the histogram of the CT numbers of the region (column 1, lines 41-48).

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Regarding claim 3, Erbel discloses the method of claim 1 wherein the CT measure is the mean of the CT numbers of the region (column 4, lines 39-54).

3. Claims 4 and 3 are rejected under 35 U.S.C. 103(a) as being unpatentable over Erbel (U S 6,792,074 B2) and Leigh et al (U S 5,402,785) as applied to claim 1 above and further in view of Cowin (U S 6,249,692 B1).

Regarding claim 4, Erbel and Leigh are silent about the specific details wherein the calibration relationship is a regression equation.

It would have been obvious to a person of ordinary skill in the art at the time the invention was made to use regression equation as taught by the Leigh in the system of Erbel because Leigh provides Erbel an improve system for non-invasive and quantitative evaluation of bone tissue in vivo.

In the same field (medical image) of endeavor, however, Cowin discloses a method for diagnosis and management of osteoporosis comprising the calibration relationship is a regression equation(column 4, lines 60-67).

Regarding claim 5, Erbel and Leigh are silent about the specific details wherein the calibrated image contains voxels expressed in density units.

In the same field (medical image) of endeavor, however, Cowin discloses a method for diagnosis and management of osteoporosis comprising the calibrated image contains voxels expressed in density units (column 5, lines 26-31).

It would have been obvious to a person of ordinary skill in the art at the time the invention was made to use voxel expressed in density unit as taught by the Cowin in the

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system of Erbel because Cowin provides Erbel an improve system for non-invasive and quantitative evaluation of bone tissue in vivo.

4. Claims 6 and 9 are rejected under 35 U.S.C. 103(a) as being unpatentable over Leigh et al (U S 5,402,785) in view of Wang et al (U S 6,052,477).

Regarding claim 6, Leigh discloses a method to calibrate the computed tomography (CT) density of tissues in x-ray computed tomography, the method acquiring at least one image containing voxels representing x-ray attenuation in the tissue, the method comprising:

locating a measurement region in at least one area of the image containing blood (column 4, lines 56-63);

determining a reference CT number of blood (column 3, lines 63-67).

However, Leigh is silent about the specific details regarding the steps of:

recording the CT numbers of the region; and,

correcting the image by the relationship between the reference CT number and the measured CT numbers of blood.

In the same field (medical image) of endeavor, however, Wang discloses automatic technique for localizing externally attached fiducial markers in volume images of the head comprising the steps of the:

recording the CT numbers of the region (column 13, lines 28-29); and,

correcting the image by the relationship between the reference CT number and the measured CT numbers of blood)column 13, lines 57-62).

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It would have been obvious to a person of ordinary skill in the art at the time the invention was made to use voxel expressed in density unit as taught by the Leigh in the system of Wang because Leigh provides Wang an improve technique which is automatic fast and knowledge-based. This automatic technique can find the centroid of fiducial markers attached to the head like MR,CT volume images, or images of any other imaging modality.

Regarding claim 9, Leigh discloses the method wherein the reference CT number of blood is measured in vitro (column 3, lines 19-21 and column 4, lines 53-55).

5. Claims 7 and 8 are rejected under 35 U.S.C. 103(a) as being unpatentable over Leigh et al (U S 5,402,785) and Wang et al (U S 6,052,477) as applied to claim 6 above and further in view of Carrol et al (U S 6,687,333 B2).

Regarding claim 7, Leigh and Wang are silent about the specific details wherein the tissue is coronary calcium.

In the same field (medical image) of endeavor, however, Carrol discloses a system for producing pulsed monochromatic X-ray comprising the tissue is coronary calcium (column 11, lines 25-28).

It would have been obvious to a person of ordinary skill in the art at the time the invention was made to use voxel expressed in density unit as taught by the Leigh in the system of Carrol because Leigh provides Carrol an improve which produces a small effective focal spot size. This system can be used with conventional X-ray detectors, such as a film, CCD, and time-of-flight detectors, or with special detectors optimized for use with the characteristics of the X-ray beam and the application.

Regarding claim 8, Leigh and Wang are silent about the specific details wherein the tissue is lung.

In the same field (medical image) of endeavor, however, Carrol discloses a system for producing pulsed monochromatic X-ray comprising the tissue is lung (column 11, lines 47-50).

It would have been obvious to a person of ordinary skill in the art at the time the invention was made to use voxel expressed in density unit as taught by the Leigh in the system of Carrol because Leigh provides Carrol an improve which produces a small effective focal spot size. This system can be used with conventional X-ray detectors, such as a film, CCD, and time-of-flight detectors, or with special detectors optimized for use with the characteristics of the X-ray beam and the application.

6. Claims 10 –14 are rejected under 35 U.S.C. 103(a) as being unpatentable over Townsend et al (U S 6,490,476 B1) in view of Leigh et al (U S 5,402,785).

Regarding claim 10, Townsend discloses a method of determining coronary calcium from computed tomography images, the images containing voxels representing x-ray attenuation of a subject's heart, the method comprising:

determining a CT number measure of at least one voxel in the heart (column 18, lines 37-41);

identifying at least one region which contains calcium(column 17, lines 14-17);

determining a CT number measure of the calcium (column 17, lines 14-17 and column 20, lines 57-63);

correcting at least one image of the heart using the heart CT number measure (column 18, lines 14-26);

establishing a calcium CT number threshold which is greater than the heart CT number measure (column 13, lines 19-29); and,

determining a calcium measure (column 17, lines 14-17 and column 20, lines 57-63);

However, Townsend is silent about the specific details regarding the steps of:

acquiring at least one image which includes the heart; and,

identifying a region of the heart;

In the same field (medical image) of endeavor, however, Leigh discloses a method for measuring perfusion-using MRI comprising the steps of:

acquiring at least one image which includes the heart (column 3, lines 47-49);
and,

identifying a region of the heart (column 14, lines 7-12).

It would have been obvious to a person of ordinary skill in the art at the time the invention was made to use locating a region of the image containing blood, measures of at least one region located within blood and combining the measurement as taught by the Leigh in the system of Townsend because Leigh provides Townsend an improve system with advantageous of the measuring perfusion of a fluid such blood into a substance such a tissue, and subjecting the fluid to electromagnetic energy so as to cause a response related to the magnetization of the fluid before it enters the substance, performing magnetic resonance measurements on the substance to

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generate intensity information and processing the intensity information to determine perfusion.

Regarding claim 11, Townsend discloses the method wherein the region of the heart is the entire heart (column 21, lines 42-45).

Regarding claim 12, Townsend discloses the method wherein the CT number measure is the mode of a histogram of the CT numbers (column 23, lines 46-48).

Regarding claim 13, Townsend discloses the method wherein the correcting means applies a smoothing algorithm which produces CT slices with mode and histogram distribution equal to the heart CT number measure (column 21, lines 51-54 and column 23, lines 42-46).

Regarding claim 14, Townsend discloses the method of wherein the CT number measure is the CT number of a voxel (column 18, lines 39-41).

7. Claims 15-19 are rejected under 35 U.S.C. 103(a) as being unpatentable over Townsend et al (U S 6,490,476 B1) in view of Wang et al (U S 6,052,477).

Regarding claim 15, Townsend discloses a method of determining tissue densities from computed tomography images, the images containing voxels representing x-ray attenuation of a subject's body, the method comprising:

segmenting a region of the image containing reference tissue (column 17, lines 31-36);

determining a CT measure of at least one voxel in the region containing reference tissue (column 18, lines 37-41);

correcting the image using at least one CT measure of the reference tissue (column 18, lines 14-26).

However, Townsend is silent about the specific details regarding the steps of:

acquiring at least one CT image of the subject's body;

recording the corrected image.

In the same field (medical image) of endeavor, however, Wang discloses automatic technique for localizing externally attached fiducial markers in volume images of the head comprising the steps of the:

acquiring at least one CT image of the subject's body (column 28-38); and,

recording the corrected image (column 13, lines 28-31).

It would have been obvious to a person of ordinary skill in the art at the time the invention was made to use voxel expressed in density unit as taught by the Townsend in the system of Wang because Townsend provides Wang an improve technique which is automatic fast and knowledge-based. This automatic technique can find the centroid of fiducial markers attached to the head like MR,CT volume images, or images of any other imaging modality.

Regarding claim 16,Townsend discloses the method wherein the reference tissue is subcutaneous fat (column 13, lines 60-62).

Regarding claim 17,Townsend discloses the method wherein the reference tissue is air (column 15, lines 52-54).

Regarding claim 18,Townsend discloses the method wherein the air is air internal to the body (column 17, lines 1-3).

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Regarding claim 19, Townsend discloses the method wherein the determining step comprises performing histogram analysis of all voxels after segmentation of the region (column 23, lines 42-48).

8. Claims 20-24 are rejected under 35 U.S.C. 103(a) as being unpatentable over Townsend et al (U S 6,490,476 B1) in view of Acharya et al (U S 6,674,834 B1).

Regarding claim 20, Townsend discloses a method to quantify calcium in the arteries of human subjects from at least one computed tomography image, the method comprising:

- scanning a reference calibration phantom containing calcium simultaneously with the subject (column 13, lines 58-60);

- calibrating at least one image pixel using the calibration phantom (column 13, lines 58-60; column 17, lines 42-50 and column 18, lines 23-26);

- locating the boundaries of blood or the heart (column 21, lines 42-45);

- determining a CT number measure of voxels within the boundaries (column 18, lines 39-40);

- determining a calibration equation which includes a slope of CT numbers in the calibration phantom and which includes an intercept determined from the CT number measure (column 13, lines 58-60);

- correcting pixels within the image by the calibration equation (column 18, lines 14-26);

- identifying voxels above a threshold value (column 18, lines 39-40).

However, Townsend is silent about the specific details regarding the step of:

- determining calcium within the arteries.

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In the same field (medical image) of endeavor, however, Acharya discloses phantom and method for evaluating calcium scoring comprising the step of the:

determining calcium within the arteries (column 4, lines 42-49).

It would have been obvious to a person of ordinary skill in the art at the time the invention was made to use determining calcium within arteries as taught by the Acharya in the system of Townsend because Acharya provides Townsend a system to reduce the total scan time required for multiple slices, a "helical" scan may be performed. The reduced scanning time, helical scanning provides other advantageous such as improved image quality and better control of contrast.

Regarding claim 21, Townsend is silent about the specific details wherein the arteries are the coronary arteries.

In the same field (medical image) of endeavor, however, Acharya discloses phantom and method for evaluating calcium scoring comprising the arteries are the coronary arteries (column 4, lines 42-49).

It would have been obvious to a person of ordinary skill in the art at the time the invention was made to use the arteries are the coronary arteries as taught by the Acharya in the system of Townsend because Acharya provides Townsend a system to reduce the total scan time required for multiple slices, a "helical" scan may be performed. The reduced scanning time, helical scanning provides other advantageous such as improved image quality and better control of contrast.

Regarding claim 22, Townsend the method wherein the locating boundaries step uses an edge threshold value which is calibrated (column 13, lines 19-29).

Regarding claim 23, Townsend the method wherein the boundaries are the three-dimensional borders of the heart (column 14, lines 31-36).

Regarding claim 24, Townsend the method wherein the best measure is the mode of the histogram of the CT numbers (column 23, lines 42-48).

Claim Rejections - 35 USC § 102

9. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

10. Claim 25 is rejected under 35 U.S.C. 102(b) as being anticipated by Gueziec et al (U S 6,301,495 B1).

Regarding claim 25 and 27-29 are Gueziec discloses a method of displaying an image of a subject, the image containing gray scale pixel values representative of tissue properties of the subject, the method comprising:

imaging a known reference simultaneously with the subject (column 5, lines 22-25);

calibrating the pixel values of the image with pixel values of the reference (column 7, lines 47-52);

defining image display gray ranges of window and level (column 5, lines 22-25), which are known in units of the known reference, the display gray levels being optimized for viewing specific image details (column 3, lines 42-45); and,

displaying the images (column 7, lines 47-52).

Regarding claim 27, Gueziec discloses the method wherein the known reference is an internal tissue of the subject (column 3, lines 33-43).

Regarding claim 28, Gueziec discloses the method wherein the imaging is magnetic resonance imaging (column 10, lines 7-13).

Regarding claim 29, Gueziec discloses the method wherein the display gray scale ranges are calibrated HU values (column 7, lines 47-52).

11. Claims 20-24 are rejected under 35 U.S.C. 103(a) as being unpatentable over Gueziec et al (U S 6,301,495 B1) in view of Acharya et al (U S 6,674,834 B1).

Regarding claim 26, Gueziec is silent about the specific details wherein the known reference is an external phantom.

In the same field (medical image) of endeavor, however, Acharya discloses phantom and method for evaluating calcium scoring comprising the arteries the known reference is an external phantom (column 4, lines 42-49).

It would have been obvious to a person of ordinary skill in the art at the time the invention was made to use the known reference is an external phantom as taught by the Acharya in the system of Gueziec because Acharya provides Gueziec a system to reduce the total scan time required for multiple slices, a "helical" scan may be performed. The reduced scanning time, helical scanning provides other advantageous such as improved image quality and better control of contrast.

Other Prior Art

12. The prior art made of record and not relied upon is considered pertinent to

applicant's disclosure.

Dillmann et al (U S 6,605,274 B1) disclose method for in vivo regulation cardiac muscle contractility.

Dixon (U S 6,372,264 B1) disclose method of reducing calcified arterial plaque buildup and cellular malfunction and for balancing ionic calcium.

Olstad (U S 5,568,811) disclose method for motion encoding of tissue structures in ultrasonic imaging.

Mattson (U S 4,779,621) discloses xenon calibration phantom.

Contact Information

13. Any inquiry concerning this communication or earlier communications from the Examiner should be directed to ABOLFAZL TABATABAI whose telephone number is (703) 306-5917.

The Examiner can normally be reached on Monday through Friday from 9:30 a.m. to 7:30 p.m. If attempts to reach the examiner by telephone are unsuccessful, the Examiner's supervisor, Mehta Bhavesh M, can be reached at (703) 308-5246. The fax phone number for organization where this application or proceeding is assigned is (703) 872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only.

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For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Abolfazl Tabatabai

Patent Examiner

Group Art Unit 2625

October 31, 2004

A-Tabatabai